DEPUTY SECRETARY OF DEFENSE

1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

AUG 16 2001

Honorable Bob Stump
Chairman, Committee on Armed Services
House of Representatives
Washington, DC 20515

Dear Mr. Chairman

The enclosed report responds to requirements contained in Section 702 of the National Defense Authorization Act for Fiscal Year 2001 regarding the Department's plan to provide chiropractic health care services and benefits for members of the Uniformed Services.

An operational framework was developed to implement chiropractic services within the Military Health System. This plan addresses patient eligibility, access to care, treatment model, determination of military medical facilities, analysis of projected cost, military readiness requirements, privileges for doctors of chiropractic, staffing methodology, transition plans and marketing requirements.

The Department met with the members of the Oversight Advisory Committee to develop the plan and will continue to consult with the committee to develop the privileges for the doctors of chiropractic and to further discuss the selection of future sites for the implementation of chiropractic care.

Thank you for your continued interest in the Military Health System.

Sincerely,

Paul Wolfowitz

Enclosure:
As stated

cc:
Honorable Ike Skelton
Ranking Democrat

Report to Congress

Report on Chiropractic Health Care Implementation Plan

Chiropractic Health Care Implementation Plan

1. Background

Section 702 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year (FY) 2001 directed the Secretary of Defense to provide chiropractic services at designated military treatment facilities (MTFs) for active duty (AD) members of the Uniformed Services. Congress also required the Secretary to complete an implementation plan for chiropractic care.

2. Program Planning

The findings of the Chiropractic Health Care Demonstration Program were considered during several working group sessions with the members of the Chiropractic Oversight Advisory Committee (OAC). The OAC includes senior representatives from the chiropractic community, the Office of the Assistant Secretary of Defense (Health Affairs), the Military Services, the General Accounting Office, and the Military Coalition. These meetings resulted in an operational framework to insure compliance with the intent of Congress to fully implement chiropractic services within DoD over a five-year period. Key points of the plan are listed below:

A. **Patient Eligibility** — In accordance with section 702(a)(1), eligible patients will be active duty personnel.

   Pregnant patients did not receive chiropractic services during the demonstration program. Members of the OAC conducted research on this issue and presented their findings at the February meeting (See Appendix A). The membership reviewed the articles and decided to recommend that pregnant AD members be eligible to receive chiropractic care under the new benefit.

   During the demonstration program, eligibility was not limited to AD personnel. Any non-AD personnel currently receiving care will be given the option of transitioning to chiropractic care outside the MHS at the individual's own expense, or to traditional care within the MHS after the October 1, 2001 implementation date. A transition plan will be developed to facilitate this change (See Section K below).

B. **Access to Care** — In accordance with section 702(a)(2)(A), access will be provided at designated MTFs (See Section D below). The scope of chiropractic services that will be accessible for active duty personnel shall include, at a minimum, care for neuro-musculoskeletal conditions. Patients will receive chiropractic services in accordance with the DoD managed care model, service implementation guidelines, and access to care standards.

Data will be collected on patients' access to chiropractic care to determine if chiropractic patients are being seen within the standard timeframe. As data are collected, staffing levels will be reviewed to adjust capacity to meet demand for services (See Section H).

C. **Treatment Model** — Patients presenting with neuro-musculoskeletal complaints shall receive chiropractic services in accordance with Service guidelines for specialty care. The OAC is developing a list of applicable ICD-9 codes.

D. **Determination of Military Medical Facilities Locations** — Chiropractic care will continue after October 1, 2001 at the current 13 MTFs that have chiropractic clinics. The staffing will remain unchanged, with two doctors of chiropractic and two assistants at each clinic based on both workload and contractual requirements. The scope of practice will expand and metrics will be collected. DoD and the Services will look for early opportunities to set up new clinics.

Decisions concerning the selection of additional sites will be made by the Services, and will take into consideration analyses and recommendations from the OAC. Criteria used in the decision-making process will include the following:

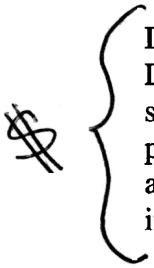
Availability of funding (See Section E below)
- Number of AD personnel served at the MTF
- Missions of the units stationed at the installation
- Estimated number of hours of chiropractic services needed
- Availability of space at the MTF and plans for future construction

Proximity of other MTFs having chiropractic services
Availability of doctors of chiropractic (DCs) to provide services
- Existing provider mix at each facility

A list of the MTFs considered for implementation of the chiropractic benefit can be found in Appendix B, Table 5, along with projected demand based on population.

As the Services collect data and refine the program models, they will determine the future sites for additional chiropractic clinics beginning with FY 03. The Services will announce their decisions no later than May 31 each year through FY 06.

E. **Analysis of Projected Cost** —The total estimated cost to DoD is based on a projected staffing requirements model (See Appendix B). This model is discussed briefly in Section H below.



It is important to note that additional funding was not appropriated for this program. DoD is providing funds out of its own resources, for the continuation of the chiropractic services at the 13 demonstration sites. Hence, while DoD would like to implement the program as early as possible, the speed of implementation will be directly affected by the availability of funds to set-up and operate each clinic. Beyond FY 02, program implementation at additional MTFs will be dependent upon the availability of funding.

F. **Military Readiness Requirements for Doctors of Chiropractic** — DoD does not yet have the data to establish the wartime readiness requirements for this program. DoD will request the Services to determine to what extent DCs might be needed in wartime. As chiropractic care becomes fully integrated with traditional treatment and DoD develops performance measurement tools, it will be better able to measure the effect of chiropractic care on readiness. It will also enable DoD, in conjunction with the chiropractic education and training community, to determine what additional skills or training would be necessary for DCs to materially contribute to the health and fitness of the fighting force. DoD will continue to monitor and evaluate contributions of chiropractic health care to the health and fitness of the fighting force.

The OAC acknowledges that the DCs bring expertise that is helpful in determining appropriate readiness roles for chiropractors. The OAC recognizes that, for example, input from the DCs on the data for neuro-musculoskeletal conditions in the operational setting would be helpful in assessing how chiropractic care supports the readiness mission.

DoD has also started the process of determining the requirements for commissioning DCs. Although legislation is currently in place authorizing their commissioning, to date the Services have not elected to do so. DoD is requesting that each Service formally review the military readiness requirements for chiropractic care and provide a paper stating its position on commissioning chiropractors.

G. **Privileges for Doctors of Chiropractic** — Privileges for DCs continue to be a matter of discussion with the OAC. The actual privileging of chiropractic providers shall be the responsibility of each MTF commander, as it is with other health professionals in accordance with appropriate Service regulations. By September 30, 2001 each Service will develop its own privileging sheets.

Privileging sheets will be developed by the Services with input from the chiropractic members of the OAC. The privileging sheets from hospitals with Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accreditation and the existing set of privileges from the chiropractic clinics at MTFs will also be used in establishing a uniform set of chiropractic privileges for existing and future chiropractic clinics. The intent of a uniform set of chiropractic privileges is to assist the MTF commanders in the establishment of a specific set of privileges for the chiropractors in their commands. Whenever possible, the OAC recommends that DCs should be involved in the privileging process.

H. **Staffing Level Methodology** — A methodology was established for the initial staffing estimates for chiropractic clinics. It is based on the beneficiary population and historical MTF workloads. The initial criteria used to determine the DCs requirement at an MTF are age-adjusted visits per 1,000 active duty personnel per year and 4,200 visits per doctor of chiropractic with one assistant. This data was based upon the scope of practice during the demonstration. It is expected that the expanded scope of practice will affect the workload and will be taken into consideration. The OAC anticipates staffing

requirements will be recomputed according to demand as the chiropractic program matures and data are collected to evaluate the program (See Appendix B).

I. **Staffing Chiropractic Clinics** We are currently examining four options of accomplishing this goal.

1. **Personal Service Contracts** — The method used for the demonstration program was to hire DCs as contract employees who provided care in the MTF. This is probably the most expeditious option, as it will allow DoD to quickly implement the benefit.

2. **Commissioning of DCs** — As mentioned in Section F above, DoD is asking the Services to determine if there is a readiness requirement for DCs to be commissioned officers.

3. **Civil Service Employees** — This option is under consideration. The concept requires detailed coordination between the health care and civilian personnel communities of DoD.

4. **Local Community Providers** — DoD is also considering the advisability of purchase of care from local civilian providers outside the MTF on a fee-for-service arrangement.

J. **Education and Training/Marketing** Materials will be provided to MTFs to assist in the education of:

- Chiropractic staff on MTF procedures
- MTF staff on the capabilities of DCs
- Unit commanders on the benefits and availability of chiropractic care

Newly assigned chiropractic staff will be provided a detailed orientation of MTF operations and procedures. Examples of this training would be an overview of the MTF's organization, how patients receive care, the use of standard administrative and clinical forms, and other protocols and guidelines necessary to function professionally at the MTF.

Education of MTF personnel will also be necessary. This might include an orientation briefing to the MTF commander and the executive staff, and more detailed information for MTF clinical personnel on the capabilities of DCs and their scope of practice.

Personnel working at MTFs with existing chiropractic clinics will be asked to review and validate the training materials. The training materials should also be in a medium available at all MTFs and available either through an Internet Web site or via mail.

A marketing and promotion program is necessary to make personnel eligible for this benefit and personnel in a position to influence their choices aware of the benefits of chiropractic care in the treatment of neuro-musculoskeletal conditions. The target audiences for marketing and promotion include:

- Active duty personnel
- Health care providers at the MTF
- Unit commanders

Promotional and marketing materials will also be reviewed and validated at MTFs with existing chiropractic clinics. The media will include handouts, posters, generic news items for post or base papers, or other similar materials.

K. **Transition Plan** — The MTFs that currently have chiropractic clinics shall develop a transition plan for non-active duty patients currently receiving chiropractic care. The Office of the Assistant Secretary of Defense (Health Affairs) will assist in providing standardized materials explaining that only active duty personnel will be eligible for the program after October 1, 2001. These materials could be provided in the form of briefings, handouts, posters, or press releases.

3. Oversight Advisory Committee Coordination

DoD is consulting with the members of the OAC on the various aspects of this project. A small group session was held in December and full committee meetings took place in January, February and March 2001 to discuss the details of the Progress Report, and to seek advice and comments on the development of the Implementation Plan. While the OAC will have satisfied its legislated mandate with the complete implementation of this plan, the Services would benefit from continued input from the chiropractic community members of the OAC.

APPENDIX A-1

SAFETY OF SPINAL MANIPULATION OF PREGNANT PATIENTS

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As has been stated elsewhere, the safety of spinal manipulation for the general population has been well-established,[1] the death rates falling far below those which are encountered in many of our most routine daily activities.[2,3]

- *Cauda equina syndrome*: Following manipulation in patients with lumbar disc herniation, consisting of neurogenic bowel and bladder disturbances, saddle anesthesia, bilaterial leg weakness, and sensory changes. The frequency of developing this condition from lumbar manipulation has been estimated to be **1 per 100 million manipulations.**[4]

- Cerebrovascular accidents: Following manipulation in patients in the upper cervical spine, involving the vertebral artery system. The frequency of developing this condition has been calculated to be **0.6 per 1 million manipulations**, half of which are fatal.[4]

These rates are 400 times *less* than the death rates observed from GI bleeding due to the use of NSAID medications[5] and 700 times lower than the overall mortality rate for spinal surgery.[6]

In terms of the management of pregnant patients in particular, it is clear from all the literature reviewed both by hand and electronically, that there is no evidence of additional risks experienced with spinal manipulation:

- A search of three computerized bibliographic databases which identified English language articles published prior to 1993 revealed 160 cases of vertebrobasilar artery dissection brought on by spontaneous onset, 115 cases occurring after spinal manipulation, and 95 cases associated with either major or trivial trauma. In only a single case [involving *spontaneous* vertebrobasilar artery dissection with no association with spinal manipulation] was a pregnant female identified.[7]

- My own search of the most extensive bibliographic database encompassing chiropractic and alternative medicine interventions yielded a total of 21 published papers describing the spinal manipulation of pregnant patients:

  a. Three of these references [two from the Journal of the American Osteopathic Association] explicitly reported that there were no complications to the fetus or [in the case of the osteopathic references] to the *patient* as well;[8-10]

  b. In none of the references were any complications described.

- Additional leading chiropractic reference textbooks on the manipulation of pregnant or pediatric patients did not indicate any additional risks of manipulation of the pregnant patient.[11,12]

In summary, a systematic survey of the literature fails to disclose any additional risk for the pregnant patient in experiencing spinal manipulation. The lack of additional complications to both the patient and the fetus is supported by a modest amount of documentation, which is provided in this communication. Given the risk factors which exist for any number of recognized and accepted activities such as driving a motor vehicle or receiving a vaccination, it would be a case of erroneous, arbitrary and capricious judgment to restrict of exclude spinal manipulations for pregnant patients based upon the evidence which exists at the present time.

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APPENDIX A-2

SAFETY OF SPINAL MANIPULATION, PARTICULARLY IN PREGNANT PATIENTS

PREPARED BY
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1. BACKGROUND

As chiropractic care in the military moves from demonstration to integration, the chiropractic members of the Chiropractic Oversight Advisory Committee (OAC) have requested that spinal manipulation services be extended to the gravid female patient, a population excluded from the demonstration project.

An overview of osteopathic medicine[1], written by an Army physician, indicates that there are approximately 1,131 osteopathic physicians on active duty, which represents approximately 20 percent of military physicians. At least some of these osteopathic physicians are currently treating pregnant patients within the Military Health System for low back pain (LBP) and sacroiliac pain (SI) pain with spinal manipulative therapy (personal communication with LCDR T. Soldo, MC, USN (DO)).

Anthony L. Rosner, Ph.D., from the Foundation for Chiropractic Education and Research conducted a review of the literature and provided invaluable information about the risks of cauda equina syndrome and cerebrovascular accidents related to spinal manipulation. Dr. Rosner references complication rates from a published systematic review of the literature by Hurwitz et al.[2]

Two important articles, which probably represent the most extreme positions on both sides of the issue, are presented to give a flavor for why it is important to understand the incidence of major and minor complications of spinal manipulation.

The first is an article by Lee et al., published in *Neurology*, that will undoubtedly come out in the privileging debate. Lee et al. report the results of a mailed survey of California neurologists experiences in dealing with neurologic complications following chiropractic manipulation. This study is not of the proper design or quality to determine the true prevalence of complications, but it will likely be used to argue the dangers of cervical spine manipulation. In this study, 177 of 486 neurologists surveyed responded to the questionnaire and reported 55 strokes, 16 myelopathies, and 30 radiculopathies that they had cared for over the preceding two years in patients who had undergone chiropractic manipulation within 24 hours of evaluation by the neurologist.[3]

On the other side of the debate will be an article by Terret et al., published in the *Journal of Manipulative and Physiological Therapies*, which cites dozens of cases where the words chiropractic or chiropractor have been used incorrectly in publications on spinal manipulation therapy by medical authors. The authors assert that, "In many cases, this is not accidental; the authors had access to original reports that identified the practitioner as a nonchiropractor."[4]

This review of the literature is undertaken to augment the work done by Dr. Rosner by providing an additional set of critical eyes looking at the literature on complications of spinal manipulation therapy. These two reviews will be useful in reducing bias enabling us to bring the inevitable debate around to the question of what is the evidence on efficacy and safety of chiropractic

services. It is hoped that this effort will assist in decisions about chiropractic privileges and implementation strategies within the Services.

2. REVIEW METHODOLOGY

A systematic review of the medical literature was conducted by Harry Taylor, MD, MPH (CDR, MC, USN) using the MESH headings "chiropractic" and ("manipulation, orthopedic" or "manipulation, spinal") and "pregnancy." MEDLINE was searched using the PubMed methodologic filter for Harm. No studies were identified. The search was then broadened to "chiropractic" alone, using the Harm filter, which yielded 16 studies when optimized for specificity and 174 studies when optimized for sensitivity. The search was repeated on Ovid with 180 studies identified using "chiropractic" + "pregnancy" in the combined Full Text, Cochrane Library, EBM, and DARE databases.

Abstracts were reviewed for relevance and validity in addressing the question of complications of spinal manipulation. During the review, it became apparent there were several published systematic reviews of the literature on the efficacy and safety of spinal manipulation (cervical and lower spine). While it was not the intent of this review to assess the efficacy of spinal manipulation, it will be important to consider effectiveness as well as risks in any balanced presentation of the evidence.

3. RESULTS

3.1 Prevalence of Back Pain in Pregnancy

Ostgaard et al. determined the point prevalence of back pain in pregnant women to be 22 to 28 percent between 12 weeks gestation to delivery with a period prevalence of any back pain in pregnancy of 49 percent.[5] Through the use of pain diagrams, this well designed prospective cohort study was able to segregate the distribution of back pain into three pain groups: (1) high back pain (HBP), (2) low back pain (LBP) and (3) sacroiliac pain (SI). Roughly 50 percent of women had SI pain, 33 percent had LBP, and the remainder had HBP. There was a statistically significant increase in SI pain over the course of pregnancy with a corresponding decrease in LBP. These results are consistent with unpublished data from a cohort study done at Naval Hospital Jacksonville (personal communication with LCDR T. Soldo, MC, USN (DO)); thus they are probably generalizable to our military population and represent the best estimate of the prevalence and distribution of back pain in pregnancy.

3.2 Efficacy of Spinal Manipulation for Low Back Pain

The DoD/VA clinical practice guideline for low back pain includes spinal manipulation as one of several treatment options for low back pain.

> Manipulation consists of techniques to increase joint and soft tissue range of motion and decrease pain. It is practiced by osteopathic physicians, specially trained and certified allopathic physicians and physical therapists. Manipulation may also be practiced by licensed chiropractors where available.

1. When used within the first month of symptoms, manipulation can be helpful for patients with acute low back problems without radiculopathy.

2. When findings suggest progressive or severe neurological deficits, an appropriate diagnostic assessment to rule out serious neurological conditions is indicated before beginning manipulation therapy. Selected patients with a nonprogressive radiculopathy may benefit from a trial of spinal manipulation.

3. There is insufficient evidence to recommend manipulation for all patients with radiculopathy.

4. A trial of manipulation in patients without radiculopathy with symptoms longer than a month is probably safe, but its efficacy is unproven."[6]

It should be noted that the quality of the available studies limits stronger statements about the efficacy of spinal manipulation.[7, 8] The DoD/VA clinical practice guideline on low back pain does not specifically address the issue of spinal manipulation in pregnancy.[6]

3.3 Incidence of Major Complications

None of the data on the prevalence of serious complications related to spinal manipulation therapy is very good because on the one hand it is difficult to determine the true denominator based on the number of spinal manipulations, various techniques and sparsity of administrative databases to mine. We know from the recent Institute of Medicine (IOM) Report that claims data, voluntary self-reporting and such underestimate the true rates of harm.

Hurwitz et al.[2] published a well-conducted systematic review of the literature on the efficacy and complications of cervical spinal manipulation.

- The authors conclude that manipulation, mobilization or physiotherapy are probably all more effective then muscle relaxants or usual medical care in producing short term pain relief among patients with subacute or chronic neck pain and that manipulation is probably slightly more effective then mobilization or physiotherapy. However, the sparsity and poor quality of the data on the effects of manipulation or mobilization for patients with headache prevent a firm conclusion from being reached.[9]

- Most of the data on complications identified by Hurwitz et al. came from 118 case reports, which is insufficient to calculate any rates.

  The best complication rate estimates found by Hurwitz et al. come from Canada where essentially 100 percent of malpractice coverage for chiropractors is by one carrier and chiropractic care is reimbursed by the Government. The major limitation of this rate, expressed algebraically below, is that it underestimates the rate of harm by relying on malpractice claims data for the numerator.

$$\frac{\text{\# Malpractice Claims Paid for Chiropractors}}{\text{\# Reimbursements for Cervical Spine Manipulation paid to Chiropractors}}$$

- Hurwitz et al. include the complication rates for GI bleeding and Cervical Spine surgery in their systematic review to emphasize the point that the rate of complications (calculated from the Canadian claims data) is very low. Care should be taken to understand the "apples vs. oranges" nature of these comparisons between claims data and hospitalization rates for GI bleeding with NSAIDS.

  I was unable to find the rate of cauda equina syndrome in the article by Hurwitz et al. Expert opinion (personal communication with Ronald Evans, DC, and a member of the OAC) indicates that the rate is so low as to make meaningful calculation difficult. In other words, there are rare case reports in the literature with tens of millions of lower back manipulations each year in the U.S. alone (90 percent of which are done by chiropractors).

Complication Rates per Hurwitz et al.

	Complication	Incidence
Cervical Spine Manipulations	Vertibrobasilar accidents or other complication*	5–10/10,000,000 manipulations
	Major impairments†	3–5/10,000,000 manipulations
	Death	<3/10,000,000 manipulations

A different method of determining the rate of complications was used by Klougart et al., where they reported the results of a survey of Danish chiropractors. This study is limited by its use of vertibrobasilar incident vice vertibrobasilar accident, the survey design with a relatively low response rate (54 percent) and method of estimating the denominator based upon a mean estimate of consultations per chiropractor-year.[10]

In this study, the rate of cerebrovascular incident (less stringent criteria then for vertibrobasilar accident) was reported as one per 120,000 cervical manipulations. Higher rates are reported for spinal manipulation of the upper neck vice the lower neck.

The introduction, Leboeuf-Yde et al. quotes rates of serious accidents following spinal manipulation of one stroke per two million treatments of the neck—based on American insurance data and one "irreversible cerebrovascular accident" per 1.3 million treatments of the neck based on a Danish study.[11] I did not review either of the articles referenced in this introduction.

The introduction to Senstad et al. estimates the risk of serious injury as less then five cases of stroke per 100,000 patients who had cervical manipulation from a chiropractor during a five year

* Other complications include spinal cord compression, vertebral fracture, tracheal rupture, diaphragm paralysis, internal carotid hematoma, and cardiac arrest.

† Major impairments include paralysis, neurologic deficit or other permanent functional impairment

period (based on an Australian study) and one case per 300,000-500,000 cervical manipulations.[12] I did not review either of the articles referenced in this introduction.

A 1996 review of cervical manipulation conducted by the RAND Corporation for the Consortium for Chiropractic Research estimated the risk of vertibrobasilar accident at 1.46/1,000,000 allowing for a 10-fold rate of under reporting.[13] This same method of correcting for a 10-fold underreporting error was used to calculate the rates of other serious complications. The rates from the RAND study probably represent the "best estimate' of risk at this time and are displayed in the attached table.

Complication Rates per 1996 RAND Report

	Complication	Incidence
Cervical Spine Manipulations	Vertibrobasilar accidents or other complication[‡]	1.46/1,000,000 manipulations
	Major impairments[§]	6.39/10,000,000 manipulations
	Death	2.68/10,000,000 manipulations

3.4 Incidence of Minor Complications

Two prospective clinic based survey studies conducted in Europe Senstad et al. Spine 1997; (22) 435-442 and Leboeuf-Yde et al. J Manipulative Physiol Ther 1997; (20) 511-5 describe the percent of patients with minor complications related to spinal manipulative therapy. These two studies report the complication rates of 1683 patients and 5970 procedures.

Senstad et al. reported on 1058 patients (4112 procedures) in Norway where 580 patients (55%) experienced 1174 minor complications with ~5% reporting more then one complication.[12]

- Leboeuf-Yde et al. reported on 625 patients (1858 procedures) in Sweden where 2754 patients (44%) experienced 508 minor complications, again with ~5 percent reporting more then one complication.[11]

[‡] Other complications include spinal cord compression, vertebral fracture, tracheal rupture, diaphragm paralysis, internal carotid hematoma, and cardiac arrest.

[§] Major impairments include paralysis, neurologic deficit or other permanent functional impairment

The types and percentages of minor complications in each study are contained in the table below:

Complication	Senstad et al.	Leboeuf-Yde et al.**
Local discomfort	53%	~65%
Headache	12%	~10%
Tiredness	11%	~10%
Radiating discomfort	10%	~10%
Dizziness	6%	<5%
Nausea	4%	<5%
Vomiting	Not included	<5%
Hot Skin	2%	Not included
Other	2%	<5%

3.5 Conclusions

While not a stated goal of this review, it is fair to say that the evidence on the efficacy of spinal manipulation is of intermediate quality and suggests that there is benefit in the treatment of low back pain and subacute/chronic neck pain.

It also appears that the rate of serious complications of spinal manipulation is low, although the data on the incidence of serious complications is of much lower quality then the efficacy data for spinal manipulation.

- The best statement about the risk of CVA/stroke for patients undergoing cervical spinal manipulation comes from the review conducted by RAND.

- Rates should be quoted as:

	Complication	Incidence
Cervical Spine Manipulations	Vertibrobasilar accidents or other complication††	1.46/1,000,000 manipulations
	Major impairments‡‡	6.39/10,000,000 manipulations
	Death	2.68/10,000,000 manipulations

- I could not find a valid rate for cauda equina syndrome and expert opinion suggests that the rate is very low (much less then the risk of death from cervical manipulation).

There is good data that back pain causes a significant burden of suffering in pregnancy.

- The point prevalence of back pain in pregnant women is 22–28 percent between 12 weeks gestation to delivery.

** Data presented in the article in such a way that exact determination of the percentage is not possible.

†† Other complications include spinal cord compression, vertebral fracture, tracheal rupture, diaphragm paralysis, internal carotid hematoma, and cardiac arrest.

‡‡ Major impairments include paralysis, neurologic deficit or other permanent functional impairment

- The period prevalence of any back pain during pregnancy is 49 percent.

  Back pain in pregnancy tends to segregate into three distinct pain groups: (1) high back pain (HBP), (2) low back pain (LBP) and (3) sacroiliac pain (SI).

- Roughly 50 percent of women have SI pain, 33 percent have LBP, and the remainder HBP.

- There is a statistically significant increase in SI pain over the course of pregnancy with a corresponding decrease in LBP.

There is good evidence about the frequency and types of common complications of chiropractic treatment.

- Approximately half to two-thirds of all individuals undergoing spinal manipulation report localized pain or tenderness after the procedure.

- Approximately 10 percent of patients report headache, tiredness, or radiating discomfort following spinal manipulation.

- Less than 5 percent of individuals reported nausea, vomiting, or dizziness.

There is no specific data to suggest that pregnant women are more or less prone to common or uncommon complications of spinal manipulation therapy.

We currently have military osteopathic physicians providing manipulation for SI and LBP during pregnancy.

4. RECOMMENDATIONS

Based on the evidence I have reviewed, the potential benefits of spinal manipulation far outweigh the risks for pregnant patients. We should allow chiropractors to treat LBP and SI pain in active duty pregnant females.

The rates of major and minor complications outlined in this review can be combined with published evidence on the efficacy of spinal manipulation to develop educational materials for MHS clinicians and patients on the risks and benefits of spinal manipulation.

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APPENDIX B

ANALYSIS OF PROJECTED COST

Section 702(a)(2)(B) of the Fiscal Year (FY) 2001 National Defense Authorization Act requires "a detailed analysis of the projected costs of fully integrating chiropractic health care services into the military health care system."

This section details the one-time and continuing costs of establishing a chiropractic clinic, based on the costs observed in the Chiropractic Health Care Demonstration Program (CHCDP). The section then details a methodology for estimating the demand for chiropractic services, again based on the demonstration program. The two are then linked to estimate the total cost of providing care to the active duty population alone.

The primary assumption made is that the costs and demand observed in the demonstration program will be similar to that under the implementation of the Active Duty benefit. Two changes in the program should be noted: under the demonstration program, only spine-related or lower back problems were to be treated; in addition contracting for chiropractic services was handled centrally. Under the implementation of the active duty benefit treatment is opened to all neuromusculoskeletal conditions, and no decision has been made regarding administration of contracts. It is likely that the demand represented in this section understates the actual demand that will be observed. The extent of this underestimate is difficult to calculate. The Health and Human Services Office of the Inspector General found chiropractic participation rates of 1.4 percent for managed care plans and 4.4 percent for fee-for-service plans, and visit counts of 7.4 for managed care and 9.4 for fee-for-service (Department of Health and Human Services Office of the Inspector General, 2000). Medicare limits chiropractic care to subluxations of the back. In a Health Maintenance Organization (HMO) setting, Hansen and Futch (1997) calculated that 5.3 percent of the enrolled managed care population sought chiropractic care, with a peak of 8.5 percent of the population in the 35 to 54 age bracket. The mean number of visits per person was 4.1 to 4.7 per year. The scope of practice was limited only to musculoskeletal conditions. These data are consistent with those estimated in the managed care setting of the MHS demonstration program, but strikingly different from those observed in fee-for-service settings. Shekelle (1991) found a mean number of visits of 11.5 per year. Hurwitz (1998) found total annual visits on the order of 1000 per thousand population. In the demonstration program, by contrast, utilization by active duty was on the order of 278 visits per thousand active duty, with about five percent of the population seeking chiropractic care.*

Therefore, it is likely that the extent of underestimation due to changes in scope of practice is small. Close monitoring of wait-times for appointments, and patient satisfaction with access is proposed for the implementation of this benefit.

* As reported in the Office of the Assistant Secretary of Defense (Health Affairs) *Final Report Chiropractic Health Care Demonstration Program* (CHCDP), February 10, 2000.

1. COSTS PER CHIROPRACTIC CLINIC

Costs can be divided into two components: one time setup costs, and continuing labor and ancillary service costs. Setup costs were derived from the demonstration program. These are shown in the first column of Table 1.

TABLE 1
COSTS ASSOCIATED WITH CHIROPRACTIC CLINIC

	Total Startup Costs	Amortized Startup	Government Personnel Cost	Direct Ancillary Costs
Fort Benning	$80,832		$306,360	$16,631
Fort Carson	$81,298		$194,673	$18,401
Fort Jackson	$80,496		$306,360	$45,999
Fort Sill	$90,350		$306,360	$1,088
WRAMC	$22,571		$230,440	$8,314
NH Jacksonville	$34,121		$306,360	$17,366
NH Lejeune	$58,421		$306,360	$6,825
NH Pendleton	$62,100		$332,090	$15,684
NNMC	$64,851		$306,360	$1,668
Scott AFB	$87,870		$248,997	$25,294
Offutt AFB	$68,833		$306,360	$18,377
Travis AFB	$82,271		$306,360	$14,568
WHMC	$27,158		$306,360	$21,675
Average	$64,706	$16,176	$289,495	$16,299
Std Error	12,624	3,156	21,340	6,285

Source: setup costs derived from CHCDP Final Report; personnel expenses and direct ancillary costs are from Medical Expenditure Reporting System (MEPRS) reports for FY00 run on February 23, 2001.

Setup costs were amortized using a straight-line depreciation over the first four years. The average amortized setup cost is $16,176. Over a four-year rollout period, this is the average cost per site for a two-person chiropractic clinic.

Continuing labor costs were estimated from existing contract costs per chiropractic clinic as reported in the MEPRS for FY 00. Ancillary expenses, or radiology, laboratory, and related orders originating in the chiropractic clinic, were also calculated from MEPRS reports for FY 00. These are also commonly termed "step down costs from D accounts." Labor costs are shown in the third column of Table 1. Ancillary expenses are shown in the fourth column of Table 1.

Since these costs were based on a two-chiropractor, two-chiropractic assistant model, all costs were divided by two to estimate the cost of a single "doctor of chiropractic (DC) unit." To some extent these costs do not "scale," fixed costs mean that it may cost nearly as much to staff a one-person clinic in terms of initial setup costs. These effects were ignored for the purposes of this cost estimate.

TABLE 2
ESTIMATED COST PER DOCTOR OF CHIROPRACTIC AND CHIROPRACTIC ASSISTANT

	Average	95 Percent Confidence Interval
Government personnel costs per DC/assistant	$144,748	15,090
Other direct costs per DC/assistant	$8,150	4,444
Setup costs for clinic	$16,176	3,156
TOTAL	$169,074	16,044

95 percent confidence interval shown reflects error in estimate assuming the CHCDP sites were a random sample of all MTFs. The result is about a 10 percent error around the estimated average cost per chiropractor.

The resulting cost estimate is shown in Table 2. Total costs per chiropractor in addition to one assistant, taking into account all relevant costs, is about $169,000 per year.

2. PROJECTED VOLUME OF CARE

In order to estimate Department of Defense (DoD) costs for chiropractic services, it is necessary to estimate the total number of visits that are likely to be demanded by the active duty population. It was further assumed that a single chiropractor plus assistant can manage 4,200 visits per year. This rate is slightly below that generated using a 20-minute visit standard, but is consistent with total visits currently observed in the demonstration program. Table 3 shows estimates of current visit counts by site for FY 00.

TABLE 3
TOTAL MEPRS REPORTED VISITS TO CHIROPRACTIC CLINICS FY00

Parent Facility Name	MEPRS Visit Total FY00
375th Med Group-Scott AFB	8,306
55th Med Group-Offutt AFB	10,368
59th Med Wing-Lackland AFB	9,614
60th Med Group-Travis AFB	6,692
Evans ACH-Fort Carson	8,125
Martin ACH-Fort Benning	6,755
Moncrief ACH-Fort Jackson	6,625
NH Camp Lejeune	8,196
NH Camp Pendleton	6,959
NH Jacksonville	8,271
NNNMC Bethesda	5,789
Reynolds ACH-Fort Sill	5,567
Walter Reed Army Medical Center	3,918

Active duty visits by age category that occurred between June 1, 1998 and June 1, 1999, were counted and divided by the estimated Active Duty population, to create average per capita visits by age. Population estimates came from the Managed Care Forecasting and Analysis System (MCFAS), the population projection program of the Military Health System (MHS). The resulting estimates by age category are shown in Table 4.

TABLE 4
ESTIMATED DEMAND FOR CHIROPRACTIC SERVICES BY ACTIVE DUTY

Age Group	Estimated Visits per Year per Thousand Population	95 Percent Confidence Interval	Population in PCM Sites
Ages 18-24	108	26	69,836
Ages 25-34	245	43	38,714
Ages 35-44	490	69	19,540
Ages 45-64	645	106	2,978

Source: Active Duty visits from six primary care manager (PCM) sites for chiropractic clinics reported in ADS taking place between 1 June 1998 and 1 June 1999; population estimates from MCFAS for FY00.

In general there is about a 25 percent margin of error around each estimate. Use of these estimates to project demand is valid only insofar as:

Demand at the PCM sites was not constrained by supply but instead driven by disease prevalence

The population at the demonstration sites was not unusual in terms of underlying prevalence or attitudes towards chiropractic

- The conditions for marketing and receptiveness towards complementary and alternative medicine can be extrapolated from the demonstration program to the DoD as a whole

Demand conditions seen in the demonstration program under the scope of practice in the demonstration program is a reasonable approximation of demand under scope of practice in the implementation

To the extent that these assumptions are not met, then actual demand in the implementation will vary.

Active Duty population at each site was calculated using MCFAS. A population profile for every standalone treatment facility was developed, using a 40-mile catchment area concept. Facilities include medical centers, community hospitals, and standalone clinics. This "custom concept" was calculated using algorithms in MCFAS. An adjustment was made to account for the "afloat population," that segment of the Navy and Marine Corps who are at sea. During these six-month deployments, fixed-facility (shore-based) care is not accessible to these

personnel. Therefore, the afloat population was calculated separately and multiplied by a scaling factor of 0.5 to account for their periodic absence from the catchment area.

Total estimated visits and the resulting estimated full-time equivalent (FTE) requirement are shown in Table 5. It is important to recall that actual distribution of resources will depend not only on revised demand and utilization data as collected during the initial implementation phases, but also on a variety of additional factors. These factors may include the following:

- importance of location relative to deploying forces
- regional sharing of resources
- ability of facility to add clinic space
- development of implementation plans at training facilities
- other factors deriving from Regional commanders and MTF commanders

The interplay of these relationships will in the end determine site location and staffing issues.

TABLE 5
ESTIMATED VISIT COUNTS AND FTE REQUIREMENT BY SITE

Facility Name	State	Total AD Pop.	Total Projected Visits	Region	Est FTE Reqmt.
Army					
Womack AMC-Fort Bragg	NC	39,262	9,399	2	2.24
Darnall ACH-Fort Hood	TX	39,672	9,297	6	2.21
Martin ACH-Fort. Benning	GA	*24,436*	*5,239*	*3*	*1.25*
Blanchfield ACH-Fort Campbell	KY	22,374	5,167	5	1.23
Walter Reed AMC-Washington DC	DC	*11,377*	*4,561*	*1*	*1.09*
Kimbrough Amb Care Cen-Fort Meade	MD	13,565	4,460	1	1.06
Winn ACH-Fort Stewart	GA	17,765	4,038	3	0.96
Madigan AMC-Fort Lewis	WA	16,435	3,991	11	0.95
Reynolds ACH-Fort Sill	OK	*16,977*	*3,952*	*6*	*0.94*
Ireland ACH-Fort Knox	KY	14,226	3,727	5	0.89
Evans ACH-Fort Carson	CO	*15,236*	*3,718*	*8*	*0.89*
Tripler AMC-Fort Shafter	HI	15,074	3,710	12	0.88
L. Wood ACH-Fort Leonard Wood	MO	17,838	3,589	8	0.85
Moncrief ACH-Fort Jackson	SC	*16,767*	*3,451*	*3*	*0.82*
Eisenhower AMC-Fort Gordon	GA	10,011	3,328	3	0.79
William Beaumont AMC-Fort Bliss	TX	11,054	2,872	7	0.68
Dewitt ACH-Fort Belvoir	VA	8,065	2,663	1	0.63
Guthrie ACH-Fort Drum	NY	10,742	2,415	1	0.57
Brooke AMC-Fort Sam Houston	TX	6,638	2,311	6	0.55
McDonald ACH-Fort Eustis	VA	7,420	2,140	2	0.51

Facility Name	State	Total AD Pop.	Total Projected Visits	Region	Est FTE Reqmt.
Army					
Irwin ACH-Fort Riley	KS	9,382	2,079	8	0.49
Munson AHC-Fort Leavenworth	KS	5,265	1,981	8	0.47
Bayne-Jones ACH-Fort Polk	LA	8,029	1,886	6	0.45
Keller ACH-West Point	NY	8,742	1,863	1	0.44
Lyster ACH-Fort Rucker	AL	4,560	1,462	4	0.35
Bassett ACH-Fort Wainwright	AK	6,259	1,451	12	0.35
Kenner ACH-Fort Lee	VA	4,280	1,308	2	0.31
Kirk ACH-Aberdeen Proving Ground	MD	2,784		1	
R W Bliss ACH - Fort Huachuca	AZ	4,621	1,289	7	0.31
Weed ACH-Fort Irwin	CA	4,626	1,141	9	0.27
Noble ACH-Fort McClellan	AL	15	5	4	0.00
Air Force					
59th Med Wing-Lackland	TX	*16,301*	*4,037*	*6*	*0.96*
11th Med Group-Bolling	DC	9,199	3,770	1	0.90
10th Med Group-USAF Academy CO	CO	12,425	3,203	8	0.76
1st Med Group-Langley	VA	8,595	2,790	2	0.66
55th Med Group-Offutt	NE	*8,317*	*2,512*	*8*	*0.60*
375th Med Group-Scott	IL	*6,242*	*2,222*	*5*	*0.53*
72nd Med Group-Tinker	OK	8,113	2,215	6	0.53
96th Med Group-Eglin	FL	7,453	2,198	4	0.52
6th Med Group-MacDill	FL	6,287	2,097	3	0.50
74th Med Group-Wright-Patterson	OH	6,210	2,051	5	0.49
16th Med Group-Hurlburt Field	FL	6,941	2,039	4	0.49
60th Med Group-Travis	CA	*7,181*	*2,017*	*10*	*0.48*
99th Med Group-O'Callaghan Hosp-Nellis	NV	7,135	1,990	7	0.47
3rd Med Group-Elmendorf	AK	6,974	1,974	12	0.47
56th Med Group-Luke	AZ	6,386	1,855	7	0.44
	AL	4,818	1,670	4	0.40
	AZ	5,825	1,668	7	0.40
Andrews	MD	*5,180*	*1,609*	*1*	*0.38*
Randolph	TX	4,389	1,605	6	0.38
78th Med Group-Robins	GA	4,952	1,584	3	0.38
305th Med Group-McGuire	NJ	5,438	1,570	1	0.37
377th Med Group-Kirtland			1,554	7	0.37
43rd Medical Group-Pope	NC	5,317	1,459	2	0.35
81st Med Group-Keesler	MS	5,613	1,437	4	0.34

Facility Name	State	Total AD Pop.	Total Projected Visits	Region	Est FTE Reqmt.
Air Force					
2nd Med Group-Barksdale	LA	5,448	1,425	6	0.34
20th Med Group-Shaw	SC	5,053	1,405	3	0.33
314th Med Group-Little Rock	AR	4,543	1,292	6	0.31
7th Med Group-Dyess	TX	4,724	1,253	6	0.30
82nd Med Group-Sheppard	TX	5,457	1,243	6	0.30
75th Med Group-Hill	UT	4,373	1,224	8	0.29
[illegible]	ND	4,700	1,175	8	0.28
p-Seymour Johnson	NC	4,264	1,123	2	0.27
366th Med Group-Mountain Home	ID	4,290	1,122	8	0.27
49th Med Group-Holloman	NM	3,974	1,060	7	0.25
436th Med Group-Dover	DE	3,804	1,005	1	0.24
Navy					
NMC Portsmouth	VA	83,073	15,663	2	3.73
NMC San Diego	CA	64,654	12,403	9	2.95
NH Camp Pendleton	CA	*41,803*	*7,989*	*9*	*1.90*
NH Pensacola	FL	30,507	7,238	4	1.72
NNMC Bethesda	MD	*22,098*	*7,165*	*1*	*1.71*
NH Camp Lejeune	NC	*38,940*	*7,113*	*2*	*1.69*
NH Jacksonville	FL	*27,605*	*5,649*	*5*	*1.34*
NH Great Lakes	IL	29,225	5,047	5	1.20
NMCL Pearl Harbor	HI	22,852	4,714	12	1.12
NH Bremerton	WA	18,133	3,250	11	0.77
NH Cherry Point	NC	12,320	2,508	2	0.60
NH Beaufort	SC	13,606	2,285	3	0.54
Navambcarecen Groton	CT	9,665	1,938	1	0.46
NH Twentynine Palms	CA	10,563	1,935	9	0.46
NH Corpus Christi	TX	7,493	1,841	6	0.44

CHCDP sites are italicized.

3. TOTAL COST ESTIMATE

The resulting FTE requirements from Table 5 can be translated into cost estimates in several ways. First, rounding all FTEs to the nearest half integer (rounding down to zero if less than 0.25 of an FTE) yields a total FTE requirement of 62.5. This in turn translates into a total cost of $11M per year, using the cost factors in Table 2. Second, rounding up all requirements to the nearest integer yields a total FTE requirement of 100, or $17M per year. These estimates are shown in Table 6.

TABLE 6
ESTIMATES OF TOTAL ANNUAL PROGRAM COST

	Total FTEs	Total Annual Cost	95 Percent Standard Error
Rounding to nearest half integer (less than 0.25 rounds to zero)	62.50	$10.57M	± 3.96M
Rounding up to nearest integer	100.00	$16.91M	± 6.34M

Reporting of total cost figures should take into account the 25 percent margin of error around estimated visits and the 10 percent margin of error around estimated costs, for a total error of plus or minus 37.5 percent.

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